DEC 1 5 2011 K112780(1/3)

7.0 510(k) SUMMARY

This 510(k) Summary for the ConforMIS iTotal® Cruciate Retaining (CR) Knee Replacement System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name and Address:	ConforMIS Inc. 11 North Ave. Burlington, MA 01804
Contact Person:	Amita S. Shah, Vice President, Quality Assurance and Regulatory Affairs
Date:	September 23, 2011
Name of Medical Device:	Device Regulation: 21 CFR 888.3560 Product Code: JWH, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis OOG, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components. Common/Usual Name: Cruciate Retaining Total Knee Replacement System Proprietary Name: ConforMIS iTotal Cruciate Retaining Knee Replacement System
Device Classification:	Class II In accordance with per 21 CFR 888.3560, a knee joint patellofemorotibial polymer/metal/polymer non-constrained cemented prosthesis is classified by the FDA as a Class II Medical Device.

Indications for Use:

The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The indications for use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The implant is intended for cemented use only.

Device Description:

The proposed iTotal CR Knee Replacement System (hereafter referred to as the "iTotal CR KRS") is a patient specific tri-compartmental faceted posterior cruciate ligament (PCL) retaining knee replacement system. The iTotal CR KRS is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component. The product is designed for bone preservation, with minimal bone resection of the tibia and femur for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. The joint restoring design provides for more natural kinematics by maintaining the patient specific femoral sagittal curves, preserving the patient specific femoral offset, preserving the medial and lateral joint lines and having a patient specific fit.

Using patient imaging (either CT or MR scans), a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The device is manufactured from cobalt chromium molybdenum ("CoCrMo") alloy. The tibial component includes a metal tray manufactured from CoCrMo alloy and either one or two polyethylene inserts manufactured from UHMWPE. The patellar component is manufactured from UHMWPE.

K112780 (3/3)

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (**K094050** cleared September 16, 2010 and **K103117** cleared January 7, 2011) and other currently marketed, cemented total knee replacement systems. The following testing was performed to establish substantial equivalence:

- Patello femoral lateral subluxation testing
- Femoral fatigue testing
- Software validation testing of proprietary software
- Cadaveric testing

Safety and Performance:

The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate device for the proposed intended use. Clinical data is not necessary to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2011

ConforMIS Incorporated
% Ms. Amita S. Shah
Vice President, Quality Assurance and Regulatory Affairs
11 North Avenue
Burlington, Massachusetts 01804

Re: K112780
Trade/Device Name: ConforMIS® iTotal Cruciate Retaining (CR) Knee Replacement System (iTotal CR KRS)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: September 23, 2011
Received: September 27, 2011

Dear Ms. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112780 (1/1)

6.0 INDICATION FOR USE STATEMENT

510(k) Number (if known): K112780

Device Name: ConforMIS® iTotal Cruciate Retaining (CR) Knee Replacement System (iTotal CR KRS)

Indications for Use:

The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The implant is intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter G. Allen for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112780